

REMARKS

Amendments

Because the Advisory Actions indicated that the amendments presented with the previous Responses After Final were not entered, and for ease of reference, the amendments as presented herein are shown relative to the specification and claims as pending at the time of the Final Office Action. The present amendments differ from the amendments filed with the "Second Response After Final" dated March 22, 2010, only in that additional claims (i.e., claims 16, 19, 22 and 23) are cancelled without prejudice or disclaimer.

Applicants note that entry of the claim amendments submitted herein is proper, because the amendments merely cancel claims or present claims in better form for appeal. Entry of the amendments is respectfully requested.

Amendment to the Specification

The "STATEMENT OF RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH" section of the specification has been amended to be in accordance with 35 U.S.C. 202 (c) (6). No new matter has been added.

Amendments to the Claims

Claim 11 is amended. Support for the claim amendment can be found throughout the application as originally filed, e.g., at page 23, lines 27-29. No new matter has been added.

Claims 16, 19, 20, 22, 23 and 35 have been cancelled without prejudice or disclaimer.

Upon entry of this amendment, claims 11, 17, 18, and 24-34 are pending in the application.

Applicants note with appreciation the indication in the April 12 Advisory Action that claims 11 and 27-34 would be allowed if the amendments submitted with the "Second Response After Final" dated March 22, 2010, were entered.

Rejections Under 35 U.S.C. § 103

(i) In the Office Action, claims 11, 16-20, 22-26 and 33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Elkhoury et al., U.S. Patent No. 5,589,480, in view of Elden, U.S. Patent No. 5,814,659, and further in view of Saito et al. (Anesthesiology, Vol. 89(6)) and Goodman and Gilman. Applicants respectfully disagree and traverse this rejection for at least the reasons discussed in previous papers (e.g., in the “Second Response After Final” dated March 22, 2010,).

Moreover, Applicants note with appreciation the statement in the April 12 Advisory Action that claims 11 and 27-34 would be allowed if the amendments submitted with the “Second Response After Final” dated March 22, 2010, were entered. The amendments filed herewith include the amendments of March 22, 2010 (and additionally cancel claims 16, 19, 22 and 23 without prejudice or disclaimer). Applicants therefore consider that the rejection has been overcome.

(ii) In the Office Action, claims 27-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Elkhoury, Elden, Saito, and Goodman as applied to claims 11, 16-20, 22-26, and 33 above, and further in view of Mayer et al. Claims 34-35 were rejected under 35 U.S.C. § 103 as being unpatentable over Elkhoury, Elden, Saito, and Goodman as applied to claims 11, 16-20, 22-26, and 33 above, and further in view of Soo et al. Again, Applicants disagree. Applicants respectfully disagree and traverse this rejection for at least the reasons discussed in previous papers (e.g., in the “Second Response After Final” dated March 22, 2010,).

Moreover, Applicants note with appreciation the statement in the April 12 Advisory Action that claims 11 and 27-34 would be allowed if the amendments submitted with the “Second Response After Final” dated March 22, 2010, were entered. The amendments filed herewith include the amendments of March 22, 2010 (and additionally cancel claims 16, 19, 22 and 23 without prejudice or disclaimer). Applicants therefore consider that the rejection has been overcome.

Accordingly, reconsideration and withdrawal of all rejections under 35 U.S.C. § 103(a) is respectfully requested.

Claims 17, 18, and 24-26

In the April 12 Advisory Action, claims 16-19 and 22-26 were rejected as allegedly “not commensurate in scope with amended claim 11 and the synergistic data submitted in the declaration filed on May 1, 2006.” Applicants disagree and traverse this rejection.

Without agreeing with the rejection, and solely to expedite prosecution, claims 16, 19, 22 and 23 have been cancelled, so the rejection of those claims is moot. As to claims 17, 18, and 24-26, Applicants respectfully submit that the ranges recited in the claims are supported by the application and are commensurate in scope with amended claim 11.

For example, claim 17 recites that the pharmaceutical composition contains morphine in a dose of about 0.1% to about 10% of the composition. Applicant notes that this amount of morphine is supported in the specification; moreover, administration of butamben in a range of about 0.04% to about 4% of the composition (i.e., at about a 1:0.4 ratio of morphine to butamben) is within ranges disclosed in the specification (see, e.g., page 17, line 23 – page 18, line 2). Similarly, claim 18 recites that the pharmaceutical composition contains morphine in a dose of about 0.5% to about 5% of the composition; administration of butamben in a range of about 0.2% to about 2% of the composition (i.e., at about a 1:0.4 ratio of morphine to butamben) is within ranges disclosed in the specification. Further, claim 24 recites that the pharmaceutical composition contains butamben in a dose of about 0.5% to about 5% of the composition, which is within ranges disclosed in the specification, and administration of morphine in a range of about 1.25% to about 12.5% of the composition (i.e., at about a 1:0.4 ratio of morphine to butamben) is also within ranges disclosed in the specification. The same argument applies to claim 25 (reciting that the pharmaceutical composition contains butamben in a dose of about 0.01% to about 1% of the composition) and claim 26 (reciting that the pharmaceutical composition contains butamben in a dose of about 0.01% to about 0.05% of the composition).

For at least the foregoing reasons, Applicants contend that each of claims 17, 18, and 24-26 is allowable, and allowance is respectfully requested.

CONCLUSION

For at least the foregoing reasons, Applicants believe the pending application is in condition for allowance. Early and favorable action is earnestly requested.

Applicants conditionally petition for any extension of time necessary for consideration of this response. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 62069DIV2 (51590).

Respectfully submitted,

Date: April 21, 2010

By: /Mark D. Russett/

Mark D. Russett, Reg. No.: 41,281
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, MA 02205
Tel. (617) 239-0100
Attorneys/Agents for Applicants
Customer No. 21874